

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Brian J. Brown, Michael Davis, David Friesen, Timothy J. Ley and Sean Skubitz
Application No.:	10/800572
Filed:	March 15, 2004
For:	Improved Longitudinally Flexible Expandable Stent
Examiner:	Vy Q. Bui
Group Art Unit:	3773

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Docket No.: S63.2N-6769-US05

APPEAL BRIEF

This is an Appeal Brief for the above-identified Application in which claims 38-40, 44-48, 50 and 52 were rejected in the Final Office Action mailed July 28, 2009. A Notice of Appeal was filed in this case on October 16, 2009. This brief is submitted in accordance with 37 CFR. § 41.37. The fees required under 37 CFR § 41.20(b)(2), and any petition for an extension of time required for filing this brief, are addressed in the accompanying Transmittal Letter.

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(i) Real Party in Interest

The Application is assigned to Boston Scientific Scimed, Inc. (formerly Scimed Life Systems, Inc.), One Scimed Place, Maple Grove, Minnesota 55311-1566, a Minnesota corporation and a subsidiary of Boston Scientific Corporation, One Boston Scientific Place, Natick, Massachusetts 01760-1537, a Delaware Corporation.

(ii) Related Appeals and Interferences

No related appeals or interferences are pending.

(iii) Status of Claims

Claims 38-41 and 43-52 are pending in the application. Claims 41 and 43 have been withdrawn from consideration. Claims 1-37 and 42 were previously canceled.

In the Advisory Action mailed September 29, 2009, the Examiner indicates that claims 49 and 51 should have been withdrawn; however, it is unclear whether or not the Examiner has actually withdrawn claims 49 and 51 from consideration. It is also unclear whether the Examiner is maintaining the objection to the specification asserted in the Final Office Action, which is discussed in this brief under Issue 3.

Claims 38-40, 44-48, 50 and 52 have been finally rejected and are the subject of this appeal. The Examiner has also objected to the specification, characterizing claims 49 and 51 as new matter. Applicants seek review of the Examiner's assertion that claims 49 and 51 contain new matter.

(iv) Status of Amendments

A Response After Final was filed on September 17, 2009, which presented arguments but did not amend the claims. No claim amendments have been filed subsequent to the Final Office Action.

(v) **Summary of Claimed Subject Matter**

A summary of the representative independent claim, as required by 37 C.F.R. § 41.37(c)(1)(v), and a non-limiting listing of locations where support may be found [bracket citations] is provided as follows:

Claim 38 is directed to a stent comprising a stent body expandable between an un-deployed orientation and a deployed orientation. [FIG. 3; page 1, lines 17 – 18]. The stent body has a longitudinal axis extending between first and second open ends. [FIG. 3; page 4, lines 19 – 20]. The stent body has a plurality of adjacent circumferential support structures being spaced-apart along the longitudinal axis. [FIGs. 5a (below) and 5b]. Each support structure including longitudinal struts being interconnected at apex portions. [FIGs. 5a and 5b]. The longitudinal struts and apex portions define an undulating pattern. [FIGs. 5a and 5b]. At least some of the apex portions of adjacent circumferential support structures are configured to longitudinally overlap one another when in the un-deployed configuration. [FIGs. 5a and 5b]. A plurality of circumferential connecting struts interconnects at least some of the adjacent circumferential support structures. [FIGs. 5a and 5b]. The circumferential connecting struts extend between the apex portions that overlap one another. [FIGs. 5a and 5b].

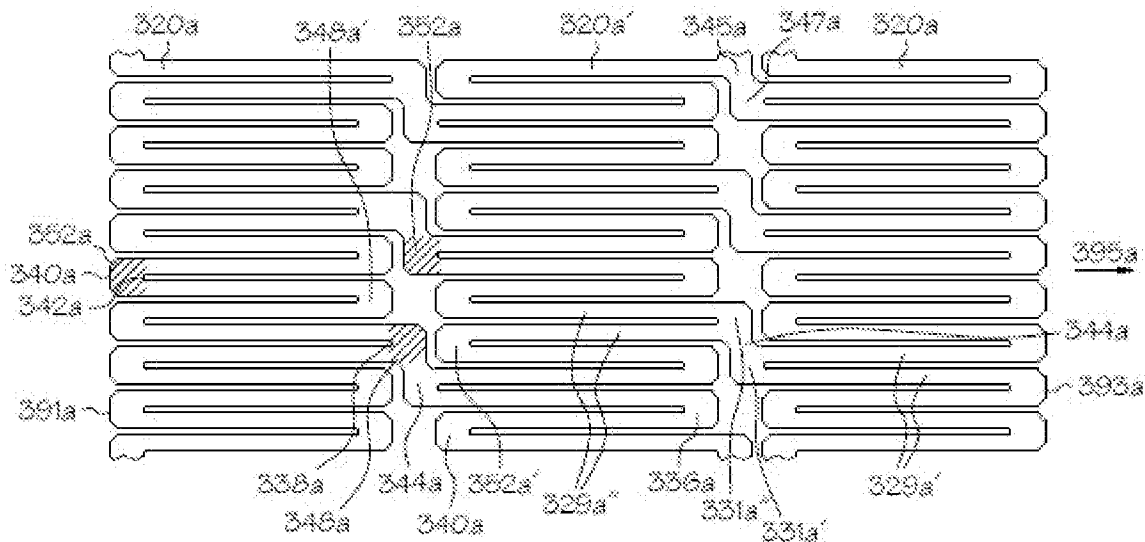


FIG. 5a

Claim 40 depends from claim 39 and requires at least some of the circumferential connecting struts to have a width greater than a width of the longitudinal struts. [FIGs. 5a and

5b].

Claim 45 is directed to a stent comprising a stent body expandable between an un-deployed orientation and a deployed orientation. [FIG. 3; page 1, lines 17 – 18]. The stent body has a longitudinal axis extending between first and second open ends. [FIG. 3; page 4, lines 19 – 20]. The stent body has a plurality of adjacent circumferential support structures spaced-apart along the longitudinal axis. [FIGs. 5a and 5b]. Each support structure includes longitudinal struts interconnected at apex portions, the longitudinal struts and apex portions defining an undulating pattern. [FIGs. 5a and 5b]. A plurality of circumferential connecting struts interconnects at least some of the adjacent circumferential support structures. [FIGs. 5a and 5b]. The circumferential connecting struts extend between the apex portions of adjacent circumferential support structures. [FIGs. 5a and 5b]. At least some of the circumferential connecting struts have a width greater than a width of the longitudinal struts. [FIGs. 5a and 5b].

Claim 46 is directed to a stent comprising a stent body expandable between an un-deployed orientation and a deployed orientation. [FIG. 3; page 1, lines 17 – 18]. The stent body has a circumference and a longitudinal axis extending between first and second open ends. [FIG. 3; page 4, lines 19 – 20]. The stent body has a plurality of circumferential support structures, which extend generally about the circumference of the stent, the circumferential support structures being spaced-apart along the longitudinal axis. [FIGs. 5a and 5b]. Each of the circumferential support structures includes longitudinal struts interconnected at apex portions, the longitudinal struts and apex portions defining an undulating pattern. [FIGs. 5a and 5b]. At least some of the apex portions of adjacent circumferential support structures being configured to longitudinally extend past each other when in the un-deployed configuration thus providing longitudinal overlap. [FIGs. 5a and 5b]. A plurality of circumferential connecting struts interconnect at least some of the adjacent circumferential support structures, the circumferential connecting struts extending between the apex portions that extend past each other. [FIGs. 5a and 5b].

Claim 48 depends from claim 46 and requires at least some of the circumferential connecting struts to have a width greater than a width of the longitudinal struts. [FIGs. 5a and 5b].

Claim 49 is directed to the stent of claim 46 wherein the adjacent circumferential

support structures include a first circumferential support structure, a second circumferential support structure and a third circumferential support structure. The second circumferential support structure is adjacent the first and the third circumferential support structures. The circumferential connecting struts joining the first and the second support structures extend in a first direction and the circumferential connecting struts joining the second and the third support structures extend in a second direction opposite the first direction. [FIGs. 5a and 5b; page 16, line 31-page 17, line 1; oppositely oriented connectors also illustrated in Figure 7].

Claim 50 is directed to the stent of claim 46 wherein some of the longitudinal struts are longer than other longitudinal struts, and wherein the longer longitudinal struts provide the longitudinal overlap at the apex portions. [FIGs. 5a and 5b].

Claim 51 is directed to the stent of claim 46 wherein the circumferential connecting struts extending between the apex portions that extend past each other are angled with respect to the circumference of the stent body. [FIG. 9; also FIGs. 5a and 5b show apex portions that extend past each other and FIGs. 4b and 6 show angled connecting struts; page 16, line 30-page 17, line 8].

(vi) Grounds of Rejection to be Reviewed on Appeal

Issue 1: Whether the Examiner erred in rejecting claims 38-40, 44-48 and 52 under 35 USC § 102, or alternatively under 35 USC § 103, over Gianturco (US 5282824).

Issue 2: Whether the Examiner erred in rejecting claim 50 under 35 USC § 103 over Gianturco.

Issue 3: Whether the Examiner erred in objecting to the Amendment filed 3/30/09, alleging that claims 49 and 51 present new matter.

(vii) Argument

Issue 1: Whether the Examiner erred in rejecting claims 38-40, 44-48 and 52 under 35 USC § 102, or alternatively under 35 USC § 103, over Gianturco (US 5282824).

The Examiner erred in rejecting claims 38-40, 44-48 and 52 under 35 USC § 102 because Gianturco does not disclose or suggest each limitation of any of the rejected claims. With respect to the rejections under 35 USC § 103, the potential modification discussed by the Examiner would not result in a device that meets the limitations of the rejected claims.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Independent claims 38, 45 and 46 each recite “circumferential support structures” that are connected by “circumferential connecting struts.”

Gianturco does not disclose or suggest “circumferential connecting struts” as required by the rejected independent claims.

The Examiner asserts that Gianturco teaches “circumferential support structures 11 and 12...interconnected by circumferential connecting strut defined by segments of member 20 (Fig. 1).” See Final Office Action at page 3 and Gianturco Figure 1, provided below.

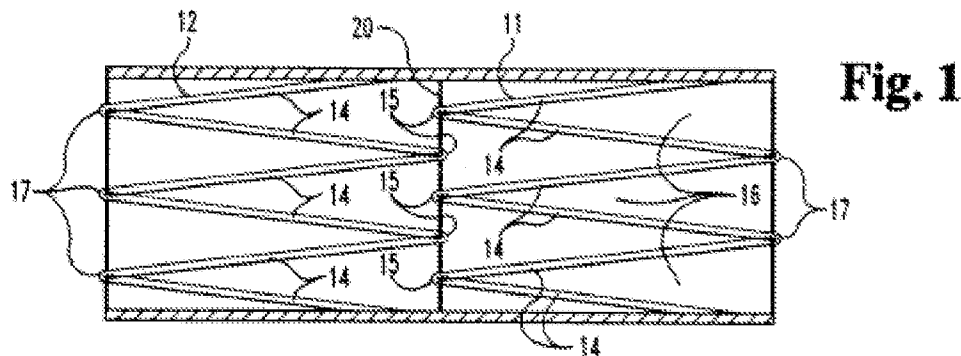



Figure 1 illustrates a thread 20 that is used to tie the adjacent stents 11 and 12 together and to prevent them from overlapping longitudinally. See column 2, line 66-column 3, line 2.

A person of ordinary skill in the art would recognize that a “circumferential connecting strut” as recited in the rejected claims must be a strut. The definition of a “strut” requires the ability to resist longitudinal compression. See e.g. definition of strut provided below,

which was also provided in the Response After Final at page 8.

strut² [struht]  Show IPA ,noun, verb, strut·ted, strut·ting.

—noun

1. any of various structural members, as in trusses, primarily intended to resist longitudinal compression. See *diags.* under KING POST, QUEEN POST.

See strut. Dictionary.com. *Dictionary.com Unabridged (v 1.1)*. Random House, Inc.

<http://dictionary.reference.com/browse/strut> (accessed: September 10, 2009).

The Gianturco segments of thread 20 that extend between joints 15 cannot be considered “struts” because they will not resist longitudinal compression. They do not meet the definition of a “strut” and will not function as a “strut.”

In the Advisory Action, the Examiner asserts that the thread 20 will inherently resist some level of compression, and could be considered a strut.

“The protocol of giving claims their broadest reasonable interpretation during examination does not include giving claims a legally incorrect interpretation. This protocol is solely an examination expedient, not a rule of claim construction.” *In re Skvorecz*, 92 USPQ2d 1020, 1024 (Fed. Cir 2009).

Although practically any material can inherently provide some (e.g. minimal) amount of compression resistance, the Gianturco thread 20 cannot provide sufficient compression resistance to be considered a strut as recited in the rejected claims. If two joints 15 were unconnected by any structural material and only air was positioned between the joints, upon moving the joints towards one another, the air would inherently provide some resistance to movement; however, airspace between two joints 15 cannot be considered a strut. A person of ordinary skill in the art would recognize that, in structural mechanics, threads, ropes and cables are considered to provide resistance to tension, but not compression. The Gianturco thread 20 is too flexible to function as a strut and would buckle under any appreciable load, including the types of loads that would be experienced in the claimed stent when used for its ordinary purpose. Thus, the Gianturco thread 20 cannot be considered the “struts” recited in the rejected claims because it cannot perform the function required of a strut under the normal operating conditions of the claimed device. A person of ordinary skill in the art would not consider the Gianturco

thread 20 to be “struts.”

Further, it is unclear whether the Gianturco joints 15 are actually attached to the thread 20 in a way that would allow any transmission of compressive forces. Gianturco discloses “serially tying eyes 18 at joints 15 with thread 20. See column 2, line 66-column 3, line 1. It is unclear whether the thread 20 is actually “tied” to the joints 15, for example using knots, or if the thread 20 is merely disposed through the eyelets 18 of the joints 15 as illustrated in Figure 1. If the connection allows the joint 15 to slide with respect to the thread 20, then no compressive-type forces can be transferred across the thread 20, which is a further reason that the thread 20 cannot be considered a claimed “strut.”

Therefore, Gianturco does not disclose or suggest a “circumferential connecting strut” as recited in the rejected independent claims, and Gianturco does not anticipate any of the rejected independent claims, or any claim dependent therefrom.

Independent claim 45 further recites, “at least some of the circumferential connecting struts having a width greater than a width of the longitudinal struts.” The Gianturco thread does not have a width that is greater than the width of a strut 14 of the stent portions 11, 12. Thus, Gianturco does not disclose or suggest a stent that meets each limitation of claim 45.

The Examiner discusses a “circumferential width” of both the struts 14 and the thread portions 20 (see Final Office Action at page 3), which the Examiner appears to interpret a span of the element in a stent circumferential direction. The Examiner’s analysis is not relevant to the claim language at issue, which does not recite any “circumferential widths,” but recites a “width” of the strut members – which would be understood by a person of ordinary skill in the art as the strut width (e.g. measurement across the strut in a direction perpendicular to the length).

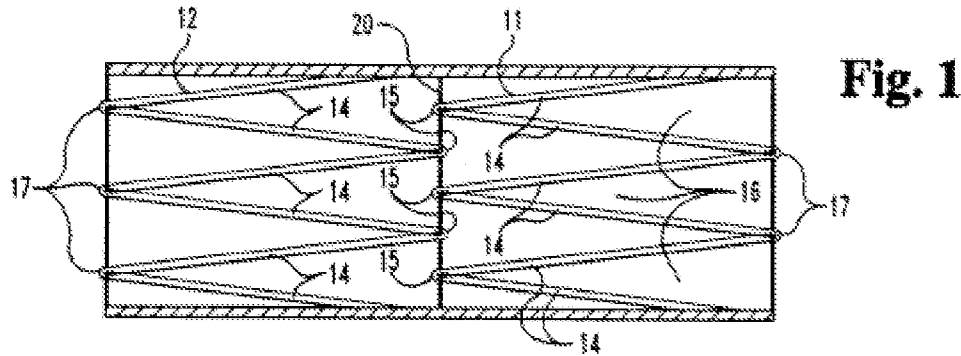
Applicants request that the Board reverse the Examiner’s rejection of claims 38-40, 44-48 and 52 under 35 USC § 102.

Alternative Rejection Under 35 USC § 103

The Examiner has not presented a *prima facie* case of obviousness because the modification proposed in the rejection would not result in a device that meets the limitations of the rejected claims.

The Examiner proposes to provide a sliding connection between the joints 15 and

the thread 20 in the Gianturco device. See Final Office Action at page 3.



If a sliding connection were used between a joint 15 and the thread 20, then no compressive-type forces could be transferred across the connection. The joints 15 would slide along the thread 20 freely. This would prevent the thread segments located between the joints from being capable of resisting any amount of compressive forces that would hold the joints 15 apart, and the thread segments could not be considered a “strut” as recited in the rejected independent claims.

Thus, the modification proposed by the Examiner would not result in a device as recited in any of the independent claims, or any claim dependent therefrom.

Applicants request that the Board reverse the Examiner’s alternative rejection of claims 38-40, 44-48 and 52 under 35 USC § 103.

Dependent Claims 40 and 48

Claim 40 recites “wherein at least some of the circumferential connecting struts have a width greater than a width of the longitudinal struts.” Claim 48 include similar limitations, as does independent claim 45, which is discussed above.

The rejection discusses “circumferential widths,” which Applicants have interpreted as discussing the span of a given Gianturco element in a circumferential direction. The rejection then asserts that, somehow, the thread 20 has a width that is greater than the width of a strut 14. See Final Office Action at page 3.

Claims 40 and 48 recite a “width” of a circumferential connecting strut as compared to a “width” of a longitudinal strut. These claims do not discuss a “circumferential width” as discussed by the Examiner. The Examiner has not explained how the thread 20, which

Issue 2: Whether the Examiner erred in rejecting claim 50 under 35 USC § 103 over Gianturco.

Claim 50 depends from independent claim 46. Under Issue 1 above, Applicants have asserted that Gianturco does not disclose or suggest a “strut” as recited in claim 46. Even if the modification to Gianturco proposed by the Examiner were performed, the resulting stent would not meet each limitation of claim 50 because the Gianturco stent does not include a “strut.”

Fig. 1

The Examiner then proposes to modify the Gianturco stent, although the specific modification proposed is unclear. The Examiner seems to propose shortening one stent member

(e.g. 12) and lengthening the other stent member (e.g. 11). Thus, the Examiner proposes to create a stent that is apparently intended to have one segment 12 positioned in a straight vessel and another segment 11 positioned in a curved vessel.

Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007).

There is no correlation between the Examiner's discussion of straight and curved vessels and the modification proposed. Even if the Examiner's assertions regarding curvature and the lengths of stent segments were supported by the record, a person of ordinary skill in the art would not have been motivated to modify Gianturco as proposed by the Examiner. If the stent were intended for a straight vessel, perhaps both segments 11, 12 might have been lengthened. If the stent were intended for a curved vessel, perhaps both segments 11, 12 might have been shortened. The Examiner has not provided any teaching that would motivate a person of ordinary skill in the art to modify one segment 11 to achieve one design goal and to also modify the other segment 12 of the same stent to achieve an opposite design goal.

The unsupported conclusory statements made by the Examiner do not amount to a *prima facie* showing that the subject matter of claim 50 would have been obvious. Applicants request that the Board reverse the Examiner's rejection of claim 50.

Issue 3: Whether the Examiner erred in objecting to the Amendment filed 3/30/09, alleging that claims 49 and 51 present new matter.

The Examiner objected to the Amendment filed 3/30/2009, alleging that newly added claims 49 and 51 present new matter. Applicants request review of the Examiner's holding of new matter on Appeal because it affects the claims. See MPEP § 608.04(c).

The immediate application was initially filed with claims 38-45, which were copied from US 2003/0055485 to Lee. The '485 application appears to have been abandoned by Lee, who filed a continuation that published as US 2008/0281404.

The Amendment filed 3/30/2009 added claims 46-52, which were copied from US 2008/0281404 – the Lee continuation.

Please note that claims 49 and 51 include limitations similar to withdrawn claims 41 and 43 (filed March 15, 2004), and that the Amendment filed 3/30/2009 stated that newly added claims 46-48, 50 and 52 are believed to read upon elected species IV, corresponding to Figure 5a.

Claim 49

The Final Office Action asserts, “The added material which is not supported by the original disclosure is as follows: claim 49: circumferential connection struts extend in two opposite directions.” See page 2.

The specification states, “The invention further contemplates embodiments in which all interconnecting elements are similarly oriented as well as embodiments in which adjacent sets of interconnecting elements extending between adjacent pairs of segments are oppositely oriented.” See page 16, line 31-page 17, line 1.

Therefore, the subject matter of claim 49 is supported by the original disclosure. Applicants request that the Board reverse the Examiner’s requirement to cancel claim 49.

Claim 51

The Final Office Action asserts, “The added material which is not supported by the original disclosure is as follows...claim 51: circumferential connection struts angled with the circumference of the stent.” See page 2.

Applicants acknowledge a potential issue of indefiniteness based upon the plain meaning of the terms used in claim 51, specifically a requirement that a “circumferential connection strut” extend at an angle to a stent circumference – i.e. extend in a direction that is not purely circumferential. However, when the meaning of “circumferential connection strut” as defined by Lee is understood, claim 51 is consistent with independent claim 46 because “circumferential connection strut” is not limited to struts that extend purely in a circumferential direction.

Independent claim 46, which recites “circumferential connection struts,” and claim 51 were copied from US 2008/0281404 to Lee in order to provoke an interference.

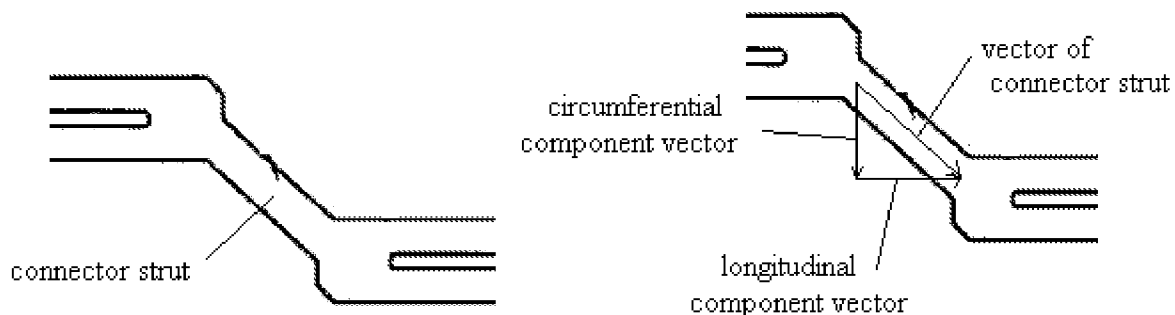
In this situation, the Examiner must adopt the definitions, meanings, and/or usages

of the terms in the copied claims *as those terms are used by Lee*, because “[w]hen interpretation is required of a claim that is copied for interference purposes, the copied claim is viewed in the context of the patent from which it was copied.” *In re Spina*, 975 F.2d 854, 858, 24 USPQ2d 1142, 1145 (Fed. Cir. 1992), citing *DeGeorge v. Bernier*, 768 F.2d 1318, 1322, 226 USPQ 758, 761 (Fed.Cir. 1985) (if claim language is ambiguous “resort must be had to the specification of the patent from which the copied claim came”). “A claim is not interpreted one way in light of the specification in which it originally was granted, and another way in light of the specification into which it is copied as a proposed interference count.” *In re Spina*, 24 USPQ2d at 1145.

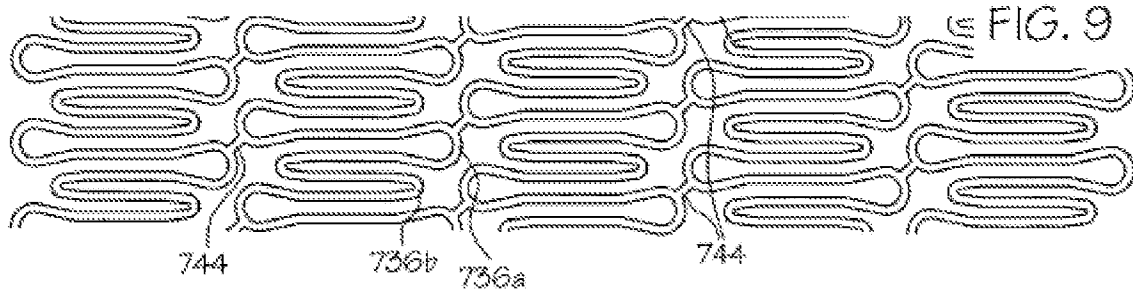
The scope of a claim term must be clearly determined by giving the claims the “broadest reasonable interpretation consistent with the specification.” See *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316, 75 USPQ2d 1321, 1329 (Fed. Cir. 2005) and MPEP § 2111.

Lee (US 2008/0281404) provides the following definition at paragraph 0022, “The phrase “circumferential connecting struts” or “circumferential connecting members” will be understood to mean struts or members that interconnect adjacent circumferential support structures 12 and **have a spacial component or vector that extends in a circumferential direction** about the stent 12” (emphasis added).

Therefore, the definition of the term “circumferential connection strut” allows for connecting elements that have a component vector extending in a circumferential direction. A “circumferential connection strut” that is angled with respect to a stent circumference, as recited in claim 51, can include a circumferential vector component and a longitudinal vector component, for example as illustrated below.



The immediate application includes several Figures that illustrate interconnecting elements that include a circumferential component vector. See e.g. Figure 4b, Figure 6 and Figure 9, and excerpt from which is provided below.



Therefore, the subject matter of claim 51 is supported by the original disclosure. Applicants request that the Board reverse the Examiner's requirement to cancel claim 51.

Argument Conclusion

Based on at least the foregoing arguments, Applicants respectfully assert that the rejections presented by the Examiner fail to establish a *prima facie* case of obviousness against any of the pending claims. Accordingly, Applicants respectfully request that the Board reverse all of the rejections asserted by the Examiner, and reverse the Examiner's requirement to cancel claims 49 and 51.

Respectfully submitted,

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(viii) Claims Appendix

38. A stent comprising: a stent body expandable between an un-deployed orientation and a deployed orientation, the stent body having a longitudinal axis extending between first and second open ends; the stent body having a plurality of adjacent closed circumferential support structures, the closed circumferential support structures being spaced-apart along the longitudinal axis; each support structure including longitudinal struts interconnected at apex portions, the longitudinal struts and apex portions defining an undulating pattern, at least some of the apex portions of adjacent closed circumferential support structures being configured to longitudinally overlap one another when in the un-deployed configuration; a plurality of circumferential connecting struts interconnecting at least some of the adjacent closed circumferential support structures, the circumferential connecting struts extending between the apex portions that overlap one another.

39. The stent of claim 38 wherein in the deployed orientation, adjacent closed circumferential support structures are offset such that the apex portions on one side of a support structure are positioned intermediate the apex portions on a facing side of an adjacent support structure.

40. The stent of claim 38 wherein at least some of the circumferential connecting struts have a width greater than a width of the longitudinal struts.

44. The stent of claim 38 wherein the undulating pattern defines a wavelength, and wherein the circumferential connecting members are at least one half the length of the wavelength.

45. A stent comprising: a stent body expandable between an un-deployed orientation and a deployed orientation, the stent body having a longitudinal axis extending between first and second open ends; the stent body having a plurality of adjacent closed circumferential support structures, the closed circumferential support structures being spaced-apart along the longitudinal axis; each support structure including longitudinal struts interconnected at apex portions, the longitudinal

struts and apex portions defining an undulating pattern; and a plurality of circumferential connecting struts interconnecting at least some of the adjacent closed circumferential support structures, the circumferential connecting struts extending between the apex portions of adjacent circumferential support structures, at least some of the circumferential connecting struts having a width greater than a width of the longitudinal struts.

46. A stent comprising: a stent body expandable between an un-deployed orientation and a deployed orientation, the stent body having a circumference and a longitudinal axis extending between first and second open ends; the stent body having a plurality of circumferential support structures, which extend generally about the circumference of the stent, the circumferential support structures being spaced-apart along the longitudinal axis; each of the circumferential support structures including longitudinal struts interconnected at apex portions, the longitudinal struts and apex portions defining an undulating pattern, at least some of the apex portions of adjacent circumferential support structures being configured to longitudinally extend past each other when in the un-deployed configuration thus providing longitudinal overlap; a plurality of circumferential connecting struts interconnecting at least some of the adjacent circumferential support structures, the circumferential connecting struts extending between the apex portions that extend past each other.

47. The stent of claim 46, wherein the adjacent circumferential support structures include a first circumferential support structure and a second circumferential support structure that is adjacent to the first circumferential support structure, and wherein in the deployed orientation, the adjacent circumferential support structures are offset such that the apex portions on one side of the first circumferential support structure are positioned intermediate the apex portions on a facing side of the second circumferential support structure.

48. The stent of claim 46, wherein at least some of the circumferential connecting struts have a width greater than a width of the longitudinal struts.

49. The stent of claim 46, wherein the adjacent circumferential support structures include a first circumferential support structure, a second circumferential support structure and a third circumferential support structure, wherein the second circumferential support structure is adjacent the first and the third circumferential support structures, and wherein the circumferential connecting struts joining the first and the second support structures extend in a first direction and the circumferential connecting struts joining the second and the third support structures extend in a second direction opposite the first direction.

50. The stent of claim 46, wherein some of the longitudinal struts are longer than other longitudinal struts, and wherein the longer longitudinal struts provide the longitudinal overlap at the apex portions.

51. The stent of claim 46, wherein the circumferential connecting struts extending between the apex portions that extend past each other are angled with respect to the circumference of the stent body.

52. The stent of claim 46, wherein the undulating pattern defines a wavelength, and wherein the circumferential connecting members are at least one half the length of the wavelength.

(ix) Evidence Appendix

None

(x) Related Proceedings Appendix

None